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25	Thr Val Ala Thr Leu Tyr Cys Val His Glu Arg Ile Glu Ile Lys Asp 93 99 105		
30	Thr Lys Glu Ala Leu Asn Lys Ile Glu Glu Glu Gln Asn Lys Ser Lys 113 119 125		
35	Lys Lys Ala Glu Glu Ala Ala Ala Asp Thr Gly His Ser Asn Glu Val 129 135 141		
40	Ser Glu Asn Tyr Pro Ile Val Glu Asn Val Glu Gly Glu Met Val His 145 151 157 163		
45	Glu Ala Ile Ser Pro Arg Thr Leu Asn Ala Trp Val Lys Val Val Glu 167 173 179 185		
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	Pro Gly Glu Met Arg Glu Pro Arg Gly Ser Asp Ile Ala Gly Thr Thr 279 285 291 297 303		
	Ser Thr Leu Glu Glu Glu Ile Gly Trp Met Thr Asn Asn Pro Pro Ile 307 313 319 325 331		
	Pro Val Gly Glu Ile Tyr Lys Arg Trp Ile Ala Leu Gly Leu Asn Lys 335 341 347 353 359		
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20	Leu Val Gly Lys Leu Asp Trp Ala Ser Glu Ile Tyr Pro Gly Ile Lys 625	630	635	640
25	Val Arg Glu Leu Cys Lys Leu Leu Asp Gly Thr Lys Ala Leu Thr His 645	650		655
	Val Ile Pro Leu Thr Glu Glu Ala Glu Leu Glu Leu Ala Glu Asp Arg 660	665		670
30	His Ile Leu Lys Glu Pro Val His Gly Val Tyr Tyr Asp Pro Ser Lys 675	680		685
35	Asp Leu Ile Ala Glu Ile Glu Lys Glu Gly Glu Ile Trp Thr Tyr 690	695		700
40	His Ile Tyr Glu Glu Pro Phe Lys Asp Leu Lys Thr Gly Lys Tyr Ala 705	710	715	720
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	Val Glu Lys Ile Thr Thr Glu Ser Ile Val Ile Trp Gly Lys Thr Pro 740	745		750
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	Glu Tyr Ala Leu Gly Ile Ile Glu Ala Glu Pro Asp Glu Ser Glu Ser 865	870	875
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30	Phe Pro Val Thr Pro Glu Val Pro Leu Arg Pro Met Thr Tyr Lys Ala 930	935	940
	Ala Val Asp Leu Ser His Phe Leu Lys Glu Lys Gly Gly Leu Glu Gly 945	950	955
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45	Gly Val Arg Tyr Pro Leu Thr Phe Gly Trp Lys Tyr Lys Leu Val Pro 995	1000	1005
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10	Gly His Glu Ala Ala Met Glu Met Leu Lys Asp Thr Ile Asn Glu Glu	193	220	225
15	Ala Ala Glu Trp Asp Arg Leu His Pro Val Glu Ala Gly Pro Ile Pro	210	215	220
20	Pro Gly Glu Ile Arg Glu Met Arg Gly Ser Asp Ile Ala Gly Thr Thr	225	230	235
	Ser Thr Pro Glu Glu Glu Leu Glu Trp Met Thr Gly Asn Pro Pro Ile	245	255	255
25	Pro Val Gly Asn Ile Tyr Lys Arg Trp Ile Ile Leu Gly Leu Asn Lys	265	265	270
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35	Pro Lys Glu Pro Phe Arg Asp Tyr Val Asp Arg Phe Lys Ala Leu	290	295	300
	Arg Ala Glu Glu Ala Thr Glu Asp Val Lys Gly Trp Met Thr Glu Thr	305	310	320
40	Leu Leu Val Glu Asn Ala Asn Pro Asp Cys Lys Ser Ile Leu Lys Ala	325	330	335
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	Arg Asn Cys Arg Ala Pro Arg Lys Lys Gly Cys Trp Lys Cys Gly Lys	405	410	415
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- 10 Glu Gly Ile Ala Ser Leu Pro Lys Glu Glu Glu Lys Asp Arg Glu Glu  
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- 15 Val Pro Pro Leu Val Ser Leu Lys Ser Leu Phe Gly Asn Asp Pro Leu  
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- 20 Ser Glu Gly Ser Pro Ile Ser Pro Ile Glu Thr Val Pro Val Thr Leu  
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- Lys Pro Gly Met Asp Gly Pro Lys Val Lys Glu Trp Pro Leu Thr Glu  
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- 30 Gly Lys Ile Ser Lys Ile Gly Pro Glu Asn Pro Tyr Asn Thr Pro Thr  
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- Phe Arg Glu Leu Asn Lys Arg Thr Glu Asp Phe Trp Glu Val Glu Leu  
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- Pro Ala Ile Phe Glu Ser Ser Met Thr Lys Ile Leu Glu Pro Phe Arg  
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	Leu Glu Leu Ala Glu Asn Arg Glu Ile Leu Lys Asp Pro Val His Gly	805	810	815	
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	Val Arg Glu Leu Ala Glu Val Val Glu Lys Val Ala Met Glu Ser Ile	865	870	875	880
45	Val Ile Trp Gly Lys Thr Pro Lys Phe Lys Leu Pro Ile Glu Lys Glu	885	890	895	
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55	Glu Trp Glu Phe Val Asn Thr Pro Pro Leu Val Lys Leu Trp Tyr Glu	915	920	925	
60	Leu Glu Lys Asp Pro Ile Leu Gly Ala Glu Thr Thr Tyr Val Asp Gly	930	935	940	
	Ala Ala Asn Arg Glu Thr Lys Leu Gly Lys Ala Gly Tyr Val Thr Asp	945	950	955	960
65	Arg Gly Arg Glu Lys Val Val Ser Leu Thr Glu Thr Thr Asn Glu Lys	965	970	975	

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- 5 Val Asn Ile Val Thr Asp Ser Gln Tyr Ala Leu Gly Ile Ile Gln Ala  
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- 15 Lys Leu Ile Gly Lys Asp Lys Ile Tyr Leu Ser Trp Val Pro Ala  
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- 30 Glu Glu Asp His Glu Arg Tyr His Ser Asn Trp Arg Thr Met Ala  
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- 40 Ser Cys Asp Lys Cys Gln Leu Lys Gly Glu Ala Met His Gly Gln  
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- 45 Val Asp Cys Ser Pro Gly Ile Trp Glu Leu Ala Gln Thr His Leu  
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- 50 His Gly Lys Val Ile Leu Val Ala Val His Val Ala Ser Gly Tyr  
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- 55 Ile Glu Ala Glu Val Ile Pro Ala Glu Thr Gly Gln Gln Thr Ala  
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- Ala Cys Trp Trp Ala Asn Ile Glu Gln Glu Phe Gly Ile Pro Tyr  
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- Asn Pro Gln Ser Gln Gly Val Val Ala Ser Met Asn Lys Glu Leu  
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- Lys Lys Ile Ile Gly Gln Val Arg Asp Gln Ala Glu His Leu Lys  
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	Lys Asp Glu Leu Asp Tyr Ala Asn Asp Ile Glu Lys Lys Ile Cys Lys	165	170	175	
45	Met Glu Lys Cys Ser Ser Val Phe Asn Val Val Asn Ser Ser Ile Gly	180	185	190	
50	Leu Gly Pro Val Thr Asn Met Glu Asn Ile Thr Ser Gly Phe Leu Gly	195	200	205	
55	Pro Leu Ser Val Leu Glu His Gly Phe His Leu Leu Thr Arg Ile Leu	210	215	220	
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	Gly Gly Ser Pro Val Cys Leu Gly Glu Asn Ser Glu Ser Pro Thr Ser	245	250	255	
65	Asn His Ser Pro Thr Ser Cys Pro Pro Ile Cys Pro Gly Tyr Arg Trp	260	265	270	

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50	Thr Pro Glu Asp Leu Asn Thr Met Leu Asn Thr Val Gly His Glu	50	55	60			
55	Ala Ala Met Glu Met Leu Lys Glu Thr Ile Asn Glu Glu Ala Ala Glu	65	70	75	80		
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65	Met Arg Glu Pro Arg Gly Ser Asp Ile Ala Gly Thr Thr Ser Thr Leu	100	105	110			
	Glu Glu Glu Ile Gly Trp Met Thr Asn Asn Pro Pro Ile Pro Val Gly	115	120	125			
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	290	295	300		
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	400	405	410		

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- 55

All references referred to in this application, including patent and patent applications, are incorporated herein by reference to the fullest extent possible.

5

Throughout the specification and the claims which follow, unless the context requires otherwise, the word 'comprise', and variations such as 'comprises' and 'comprising', will be understood to imply the inclusion of a stated integer, step, group of integers or group of steps but not to the exclusion of any other integer, step, group of integers or group of steps.

10

The application of which this description and claims forms part may be used as a basis for priority in respect of any subsequent application. The claims of such subsequent application may be directed to any feature or combination of features described herein. They may take the form of product, composition, process, or use claims and may include, by way of example and without limitation, the following claims:

15

Claims

1. A method of raising an immune response against a pathogen which comprises administering (i) one or more first immunogenic polypeptides derived from said pathogen; (ii)  
5 one or more adenoviral vectors comprising one or more heterologous polynucleotides encoding one or more second immunogenic polypeptides derived from said pathogen; and (iii) an adjuvant; wherein the one or more first immunogenic polypeptides, the one or more adenoviral vectors and the adjuvant are administered concomitantly.
2. A method of raising an immune response against a pathogen which comprises  
10 administering (i) one or more first immunogenic polypeptides derived from said pathogen co-formulated with an adjuvant; and (ii) one or more adenoviral vectors comprising one or more heterologous polynucleotides encoding one or more second immunogenic polypeptides derived from said pathogen; wherein one or more immunogenic polypeptides and adjuvant, and one or more adenoviral vectors are administered concomitantly.
- 15 3. A method of stimulating the production of pathogen-specific CD4+ and/or CD8+ T-cells and/or antibodies in mammals which comprises administering to said mammal (i) one or more first immunogenic polypeptides derived from a pathogen; (ii) one or more adenoviral vectors comprising one or more heterologous polynucleotides encoding one or more second  
20 immunogenic polypeptides derived from said pathogen; and (iii) an adjuvant; wherein the one or more first immunogenic polypeptides, the one or more adenoviral vectors and the adjuvant are administered concomitantly, for example by administering an immunologically effective amount of an aforesaid composition.
4. A method of raising an immune response against a pathogen which consists of (a) administering (i) one or more first immunogenic polypeptides derived from said pathogen; (ii)  
25 one or more adenoviral vectors comprising one or more heterologous polynucleotides encoding one or more second immunogenic polypeptides derived from said pathogen; and (iii) an adjuvant, wherein the one or more immunogenic polypeptide, the one or more adenoviral vector and the adjuvant are administered concomitantly; and (b) optionally repeating the steps of (a).
5. A method of raising an immune response against a pathogen which comprises  
30 administering (i) one or more first immunogenic polypeptides derived from said pathogen; (ii) one or more adenoviral vectors comprising one or more heterologous polynucleotides encoding one or more second immunogenic polypeptides derived from said pathogen; and (iii) an adjuvant; wherein the one or more first immunogenic polypeptides, the one or more adenoviral vectors and the adjuvant are administered concomitantly; and wherein the method does not  
35 involve administering any priming dose of immunogenic polypeptide or polynucleotide encoding immunogenic polypeptide.

6. A method according to any one of claims 1 to 5 wherein one or more immunogenic polypeptides, one or more adenoviral vectors and an adjuvant are co-formulated.
7. A method according to any one of claims 1 to 5 wherein production of pathogen specific CD4+ T-cells and CD8+ T-cells and antibodies is stimulated.
- 5 8. A vaccine composition comprising (i) one or more first immunogenic polypeptides derived from a pathogen; (ii) one or more adenoviral vectors comprising one or more heterologous polynucleotide encoding one or more second immunogenic polypeptides derived from said pathogen; and (iii) an adjuvant.
9. A method or vaccine composition according to any one of claims 1 to 8 wherein one or  
10 more of said one or more first immunogenic polypeptides is substantially the same as one or more of said one or more second immunogenic polypeptides.
10. A method or vaccine composition according to any one of claims 1 to 8 wherein one or more of said one or more first immunogenic polypeptides contains at least one antigen which is substantially the same as an antigen contained in one or more of said one or more second  
15 immunogenic polypeptides.
11. A method or vaccine composition according to any one of claims 1 to 10 wherein one or more the first immunogenic polypeptides comprises at least one T cell epitope.
12. A method or vaccine composition according to any one of claims 1 to 11 wherein the one or more first immunogenic polypeptide comprises at least one B cell epitope.
- 20 13. A method or vaccine composition according to any one of claims 1 to 12 wherein one or more of said one or more first immunogenic polypeptides and one or more of said one or more second immunogenic polypeptides share one or more identical B-cell and/or T-cell epitopes.
14. A method or vaccine composition according to any one of claims 1 to 8 wherein none of the one or more of said one or more first immunogenic polypeptides is substantially the same as  
25 or contains any antigen in common with one or more of said one or more second immunogenic polypeptides.
15. A method or vaccine composition according to any one of claims 1 to 14 wherein one or more of the adenoviral vectors is derived from a human adenovirus.
16. A method or vaccine composition according to claim 15 wherein the human adenovirus  
30 serotype is selected from Ad1, Ad2, Ad4, Ad5, Ad6, Ad11, Ad 24, Ad34 and Ad35.
17. A method or vaccine composition according to any one of claims 1 to 14 wherein one or more of the adenoviral vectors is derived from a non-human primate adenovirus.
18. A method or vaccine composition according to claim 17 wherein the non-human primate adenovirus serotype is selected from chimpanzee adenovirus serotypes Pan5, Pan6, Pan7 and  
35 Pan9.
19. A method or vaccine composition according to any one of claims 1 to 18 wherein the pathogen is HIV.

20. A method or vaccine composition according to claim 19 wherein the immunogenic polypeptides contain HIV derived antigens which are selected from Env, Nef, Gag, and Pol and immunogenic derivatives thereof and immunogenic fragments thereof.
21. A method or vaccine composition according to claim 20 wherein a first immunogenic polypeptide is p24-RT-Nef-p17.
22. A method or vaccine composition according to claim 20 or claim 21 wherein a second immunogenic polypeptide is Gag-RT-Nef.
23. A method or vaccine composition according to any one of claims 1 to 18 wherein the pathogen is *Plasmodium falciparum* and/or *Plasmodium vivax*.
24. A method or vaccine composition according to claim 23 wherein the immunogenic polypeptides contain antigens derived from *Plasmodium falciparum* and/or *Plasmodium vivax* which are selected from circumsporozoite (CS) protein, MSP-1, MSP-3, AMA-1, LSA-1, LSA-3 and immunogenic derivatives thereof or immunogenic fragments thereof.
25. A method or vaccine composition according to claim 24 wherein a/the immunogenic polypeptide is the hybrid protein RTS.
26. A method or vaccine composition according to claim 25 wherein RTS is presented in the form of a mixed particle known as RTS,S.
27. A method or vaccine composition according to any one of claims 24 to 26 wherein a/the immunogenic polypeptide encoded by a polynucleotide is the CS protein from *Plasmodium falciparum* or immunogenic fragment thereof.
28. A method or vaccine composition according to any one of claims 1 to 18 wherein the pathogen is *Mycobacterium tuberculosis*.
29. A method or vaccine composition according to any one of claims 1 to 28 wherein the adjuvant comprises a preferential stimulator of Th1 responses.
30. A method or vaccine composition according to claim 29 wherein the adjuvant comprises QS21 and/or 3D-MPL and/or CpG.
31. A method or vaccine composition according to claim 30 wherein the adjuvant comprises QS21 and 3D-MPL.
32. A method or vaccine composition according to any one of claims 1 to 31 wherein the adjuvant contains an oil-in-water emulsion.
33. A method or vaccine composition according to any one of claims 1 to 31 wherein the adjuvant contains liposomes.
34. A method of stimulating an immune response in a mammal which comprises administering to a subject an immunologically effective amount of a vaccine composition according to any one of claims 8 to 33.
35. Use of a vaccine composition according to any one of claim 8 to 33 in the manufacture of a medicament for stimulating an immune response in a mammal.



36. A vaccine composition according to any one of claims 8 to 33 for use in stimulating an immune response in a mammal.

37. A kit comprising (i) one or more first immunogenic polypeptides derived from a pathogen; (ii) one or more adenoviral vectors comprising one or more heterologous

5 polynucleotides encoding one or more second immunogenic polypeptides derived from said pathogen; and (iii) an adjuvant.

38. A kit comprising (i) one or more first immunogenic polypeptides derived from a pathogen and an adjuvant; and (ii) one or more second adenoviral vectors comprising one or more heterologous polynucleotides encoding one or more immunogenic polypeptides derived

10 from said pathogen.

39. A method, or vaccine, or kit, or use according to any preceding claim wherein the first immunogenic polypeptide comprises p24-RT-Nef-p17, the adjuvant comprises 3D-MPL and QS21 in a liposome such as adjuvant B hereon, and the adenoviral vector comprises a chimpanzee adenovirus serotype Pan7 vector comprising a polynucleotide encoding the immunogenic polypeptide Gag-RT-Nef, optionally codon optimised.

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40. A method, or vaccine, or kit, or use according to any preceding claim wherein one, or two, or all of the polypeptide, adenoviral vector and adjuvant components are combined with a pharmaceutically acceptable excipient.

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Figure 3a

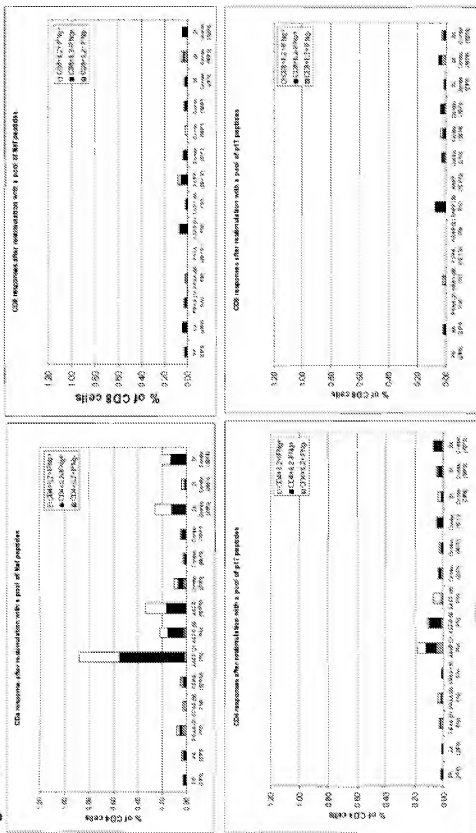
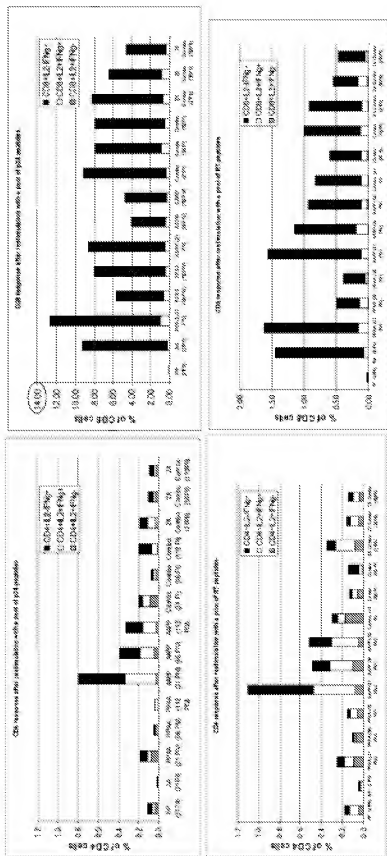


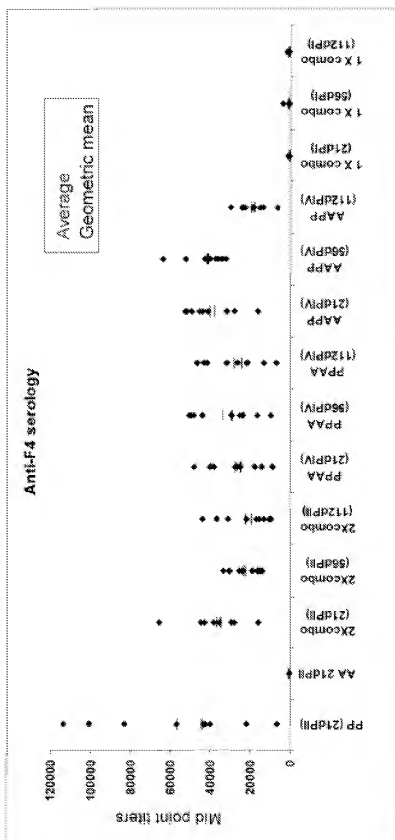
Figure 3b

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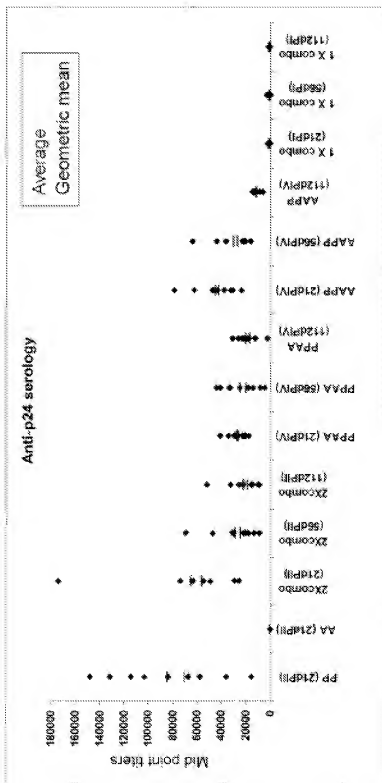
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Figure 4



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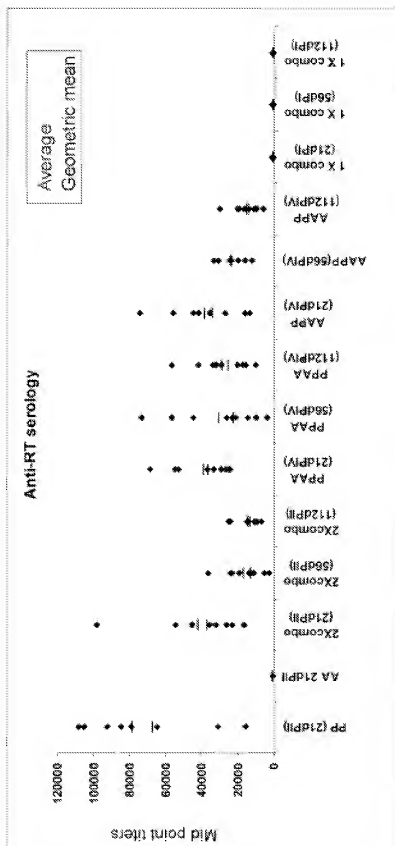
Figure 5





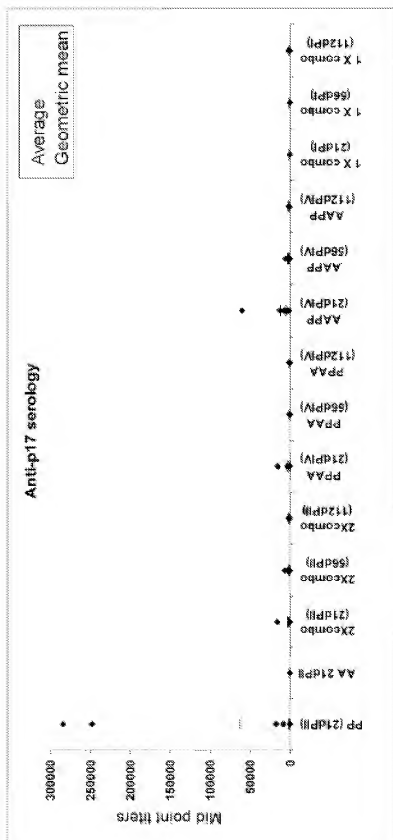
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Figure 6



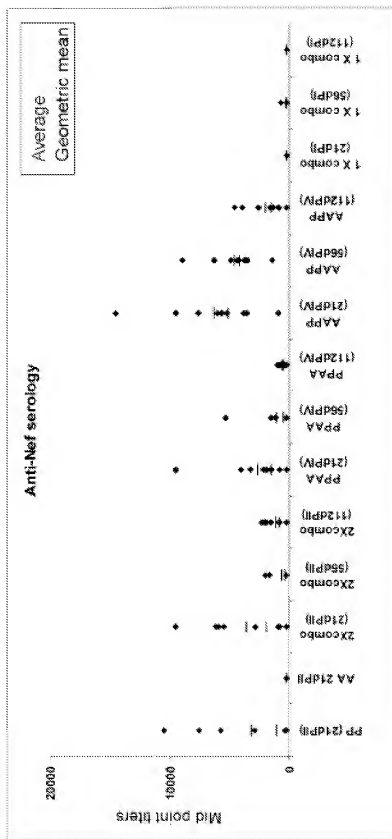
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Figure 7



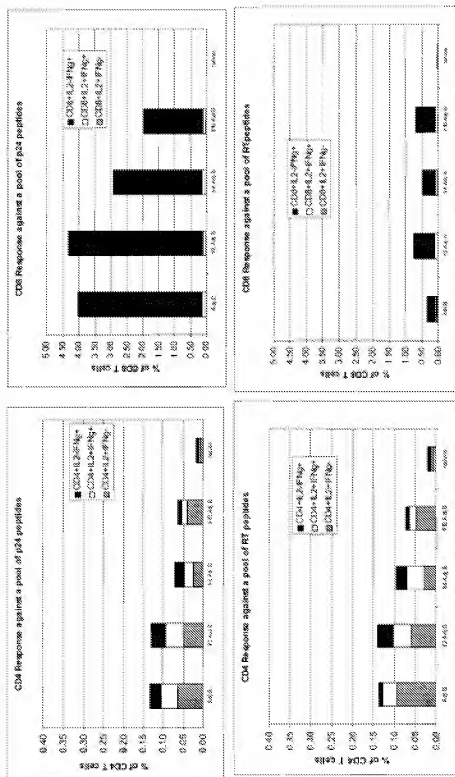
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Figure 8



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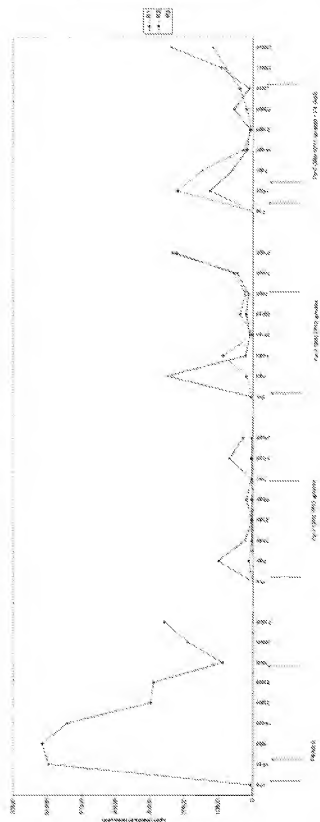
Figure 9



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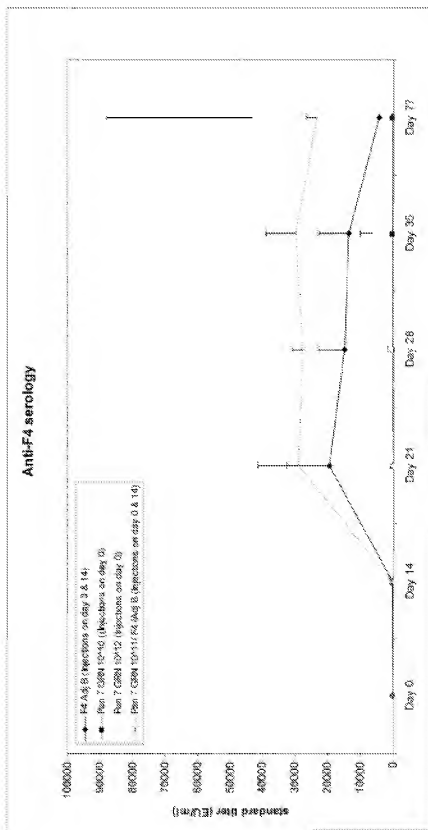
Figure 10

Lymphoproliferative response of rabbit PBMC against peptide pools covering F4 sequence



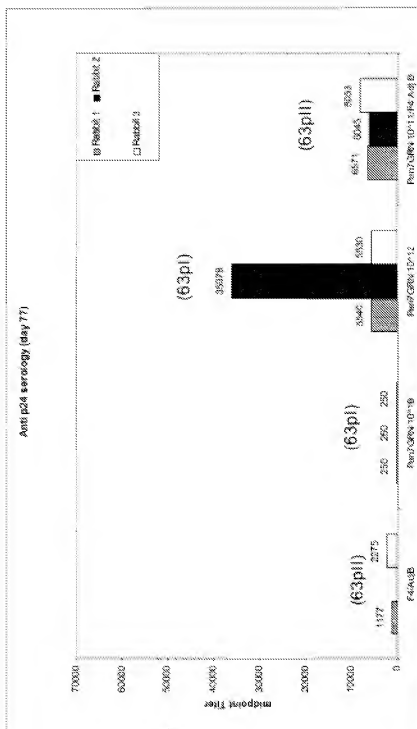
13/27

Figure 11



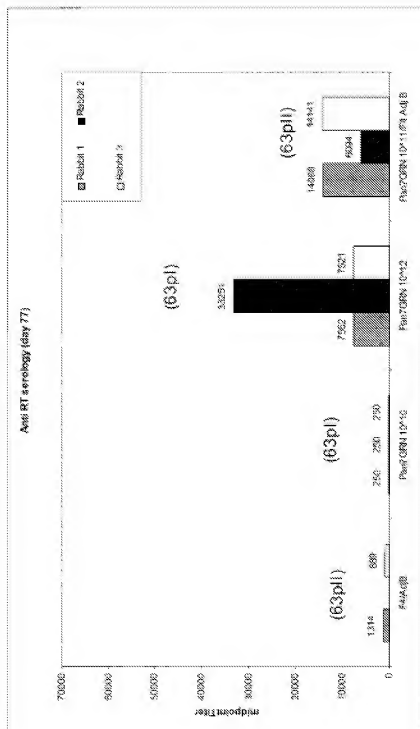
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Figure 12a



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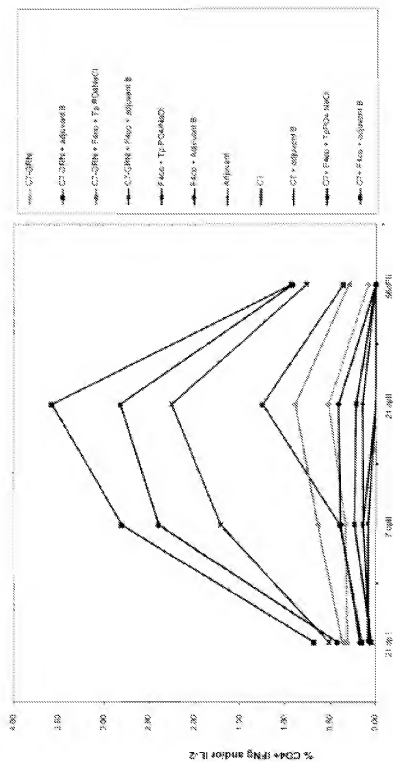
Figure 12b





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Figure 13





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Figure 15A

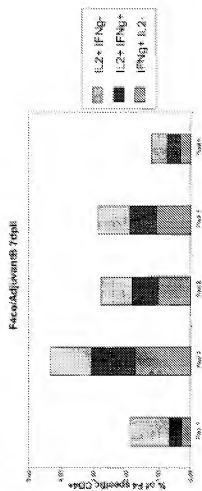
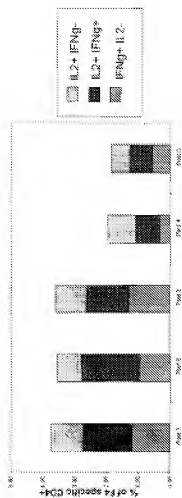


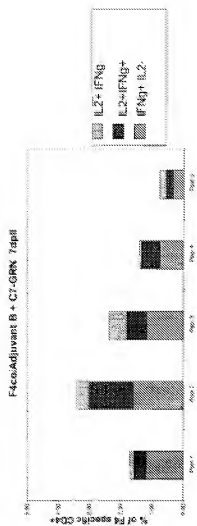
Figure 15B

F4co/AdjuvantB + C\*empty 7dpi



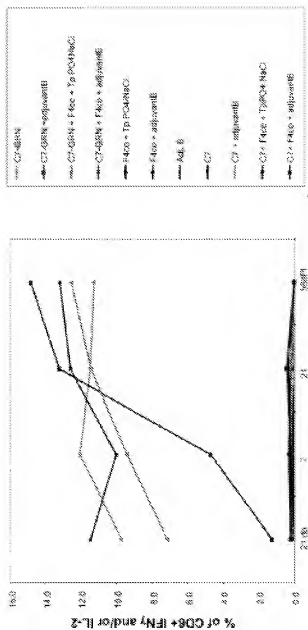
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Figure 15C



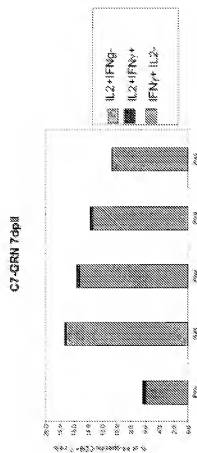
20/27

Figure 16



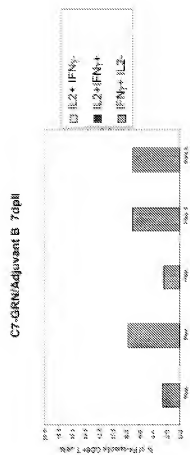
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Figure 17A



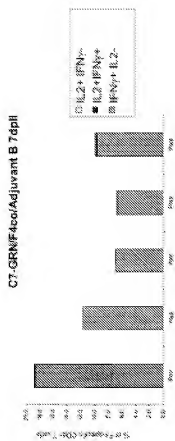
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Figure 17B



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Figure 17 C





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Figure 18

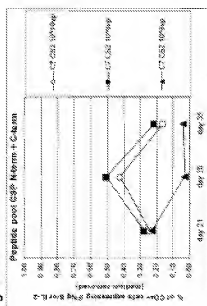
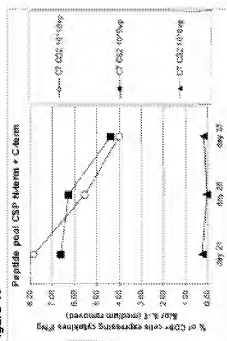


Figure 19



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Figure 20

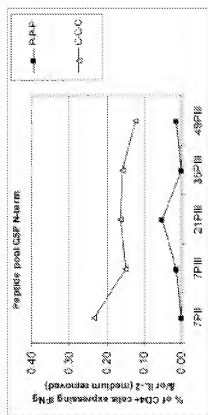
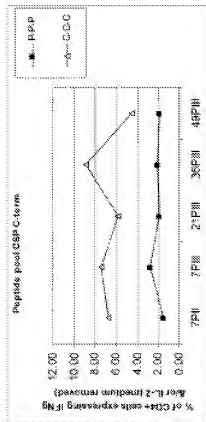


Figure 21



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Figure 22

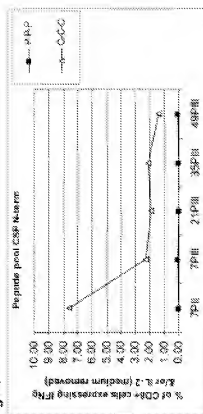
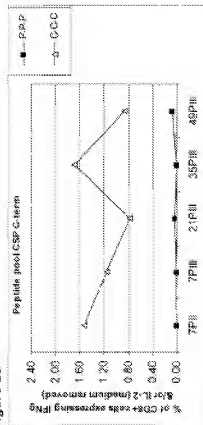
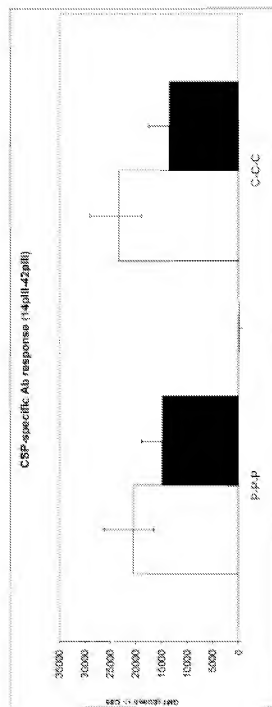


Figure 23



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Figure 24



## INTERNATIONAL SEARCH REPORT

International application No  
PCT/EP2008/052449

## A. CLASSIFICATION OF SUBJECT MATTER

INV. C07K14/16 C07K14/445 C12N15/861 A61K39/00

According to International Patent Classification (IPC) or to EPO national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

C07K A61K C12N

Documentation searched other than minimum documentation to the extent that such documents are indicated in the fields searched

Electronic data base consulted during the international search (system of data base and, where practical, search terms used)

EPO-Internal, EMBASE, BIOSIS, WPI Data

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2004/110482 A (ISIS INNOVATION [GB]; HILL ADRIAN [GB]; MOORE ANNE C [GB]; NICOLL CLAI) 23 December 2004 (2004-12-23) the whole document	1-15, 19, 28, 34-38, 40
Y		16-18, 20-27, 29-33
Y	WO 02/22080 A (MERCK & CO INC [US]; EMINI EMILIO A [US]; YOUSIL RIMA [US]; BETT ANDREW) 21 March 2002 (2002-03-21) page 22, lines 4-17 the whole document	16-18
Y	WO 2006/120034 A (GLAXO GROUP LTD [GB]; ERTL PETER FRANZ [GB]; TITE JOHN PHILIP [GB]; VA) 16 November 2006 (2006-11-16) the whole document	16-18, 20, 22

-/-

☒ Further documents are listed in the continuation of Box C.☒ See patent family series.

## \* Special categories of cited documents:

\*A\* document defining the general state of the art which is not considered to be of particular relevance

\*E\* earlier document but published on or after the international filing date

\*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another claim(s) or other special reason (as specified)

\*O\* document relating to an oral disclosure, use, exhibition or other means

\*P\* document published prior to the international filing date but later than the priority date claimed

\*T\* later documents published after the international filing date or priority date and not in conflict with the application but claim to disavow the principle or theory underlying the invention

\*X\* document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

\*Y\* document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is compared with one or more other such documents, such combination being obvious to a person skilled in the art

\*Z\* document member of the same patent family

Date of the actual completion of the international search

29 May 2008

Date of mailing of the international search report

16/06/2008

Name and mailing address of the ISA

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Authorized officer

Irton, Andrea

## INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2008/052448

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2006/013106 A (GLAXOSMITHKLINE BIOLOG SA [BE]; ABRECHT HELGE [BE]; DELCHAMBRE MARTINE) 9 February 2006 (2006-02-09) the whole document	20, 21, 29-33
Y	WO 2007/003384 A (GLAXOSMITHKLINE BIOLOG SA [BE]; COHEN JOSEPH D [BE]) 11 January 2007 (2007-01-11) the whole document	23-27, 29-33
Y	GANNE V ET AL: "Enhancement of the efficacy of a replication-defective adenovirus-vectored vaccine by the addition of oil adjuvants" VACCINE, BUTTERWORTH SCIENTIFIC, GUILDFORD, GB, vol. 12, no. 13, 1 January 1994 (1994-01-01), pages 1190-1196, XP002393618 ISSN: 0264-410X the whole document table 1	32

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/EP2008/052468

## Box No. II Observations where certain claims were found unsearchable (Continuation of Item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:  
Although claims 1-7, 9-34, 39, and 40 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements in such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 26(4).

## Box No. III Observations where unity of invention is lacking (Continuation of Item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, the Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; 2 is covered by claims Nos.:

### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

## INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2008/052448

Patent document cited in search report		Publication date		Patent family member(s)	Publication date
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			KR	20070041765 A	19-04-2007
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			EP	1896060 A1	12-03-2008